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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/029,009	12/19/2001	Jason S. Felsch	111025.173	3244
26161	7590	10/01/2004	EXAMINER	
FISH & RICHARDSON PC 225 FRANKLIN ST BOSTON, MA 02110			LOCKARD, JON MCCLELLAND	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/029,009	FELSCH ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jon M Lockard	1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____  | 6) <input type="checkbox"/> Other: ____                                     |

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-20 and 37-38, drawn to methods of identifying a ligand for a hydrophobic protein, classified in class 436, subclass 501, for example.
- II. Claims 21-30 and 39, drawn to methods of isolating a hydrophobic protein, classified in class 435, subclass 7.1, for example.
- III. Claims 31-36 and 40, drawn to nucleic acid molecules and vectors suitable for hydrophobic protein expression, classified in class 536, subclass 23.5 and class 435, subclass 320.1, for example.

The inventions are distinct, each from the other because of the following reasons:

The various methods of Inventions I and II are drawn to patentably distinct methods. Although there are no provisions under the section for "Relationship of Inventions" in MPEP § 806.05 for Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentable distinct inventions for the following reasons: Inventions I and II are directed to methods that are distinct both physically and functionally, have different method steps, starting compounds, and goals, are not required one for the other, and require non-coextensive searches.

Therefore, a search and examination of all the methods of Invention I-II in one patent application would result in an undue burden, since the searches for the Inventions' methods are not co-extensive.

Inventions III and each of Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case Invention III is distinct from and unrelated to Inventions I and II, wherein the nucleic acids of Invention III is

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neither made by nor used in the methods of Inventions I and II, and wherein each does not require the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, recognized divergent subject matter, and/or separate search requirement, restriction for examination purposes as indicated is proper.

### ***Species Election***

#### **Invention I**

This application contains claims directed to the following patentably distinct species of the claimed invention:

If Invention I is elected, three separate species requirements are set forth. Applicants must select **(a)** one of the following species of hydrophobic target proteins: SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, or SEQ ID NO:23. Although classifications for the proteins are overlapping, each represents a patentably distinct species, having different sequences and structures, and requiring separate sequence searches. Search of more than one sequence would constitute a burden on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4, 6-7, and 9-11 are generic.

Additionally if Invention I is elected, Applicants must also select **(b)** one of the following species of amphiphiles: a polar lipid, an amphiphilic macromolecular polymer, a surfactant or detergent, or an amphiphilic polypeptide. Each amphiphile is considered to constitute a patentably distinct species because they are different chemical compounds with different structures, and require separate searches. Search of more than one compound would constitute a burden on the Office.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4, 6-7, and 9-11 are generic.

Furthermore, if Invention I is elected, Applicants must also select (c) one of the following species of epitope tags: SEQ ID NO:29, SEQ ID NO:30, SEQ ID NO:31, SEQ ID NO:32, or SEQ ID NO:33. Although classifications for the epitope tags are overlapping, each represents a patentably distinct species, having different sequences and structures, and requiring separate sequence searches. Search of more than one sequence would constitute a burden on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4, 6-7, and 9-11 are generic.

Applicant is advised that a reply to this requirement must include an identification of the single species that is elected consonant with each of the three species election requirements, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

## **Invention II**

This application contains claims directed to the following patentably distinct species of the claimed invention:

If Invention II is elected, three separate species requirements are set forth. Applicants must select (a) one of the following species of hydrophobic target proteins: SEQ ID NO:7, SEQ ID NO:8, SEQ ID NO:9, SEQ ID NO:10, SEQ ID NO:11, SEQ ID NO:19, SEQ ID NO:20, SEQ ID NO:21, SEQ ID NO:22, or SEQ ID NO:23. Although classifications for the proteins are overlapping, each represents a patentably distinct species, having different sequences and structures, and requiring separate sequence searches. Search of more than one sequence would constitute a burden on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 21 is generic.

Additionally, if Invention II is elected, Applicants must also select (b) one of the following species of epitope tags: SEQ ID NO:29, SEQ ID NO:30, SEQ ID NO:31, SEQ ID NO:32, or SEQ ID NO:33. Although classifications for the epitope tags are overlapping, each represents a patentably distinct species, having different sequences and structures, and requiring separate sequence searches. Search of more than one sequence would constitute a burden on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 21 is generic.

Applicant is advised that a reply to this requirement must include an identification of the single species that is elected consonant with each of the two species election requirements, and a listing of all

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claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

### **Invention III**

This application contains claims directed to the following patentably distinct species of the claimed invention:

If Invention III is elected, three separate species requirements are set forth. Applicants must select (a) one of the following species of hydrophobic target proteins: SEQ ID NO:19, SEQ ID NO:20, a membrane protein, an integral membrane protein, a transmembrane protein, a monotopic membrane protein, a polytopic membrane protein, a pump protein, a channel protein, a receptor kinase protein, a G protein-coupled receptor, a membrane-associated enzyme, or a transporter protein. Although classifications for the proteins are overlapping, each represents a patentably distinct species, having different sequences and structures, and requiring separate sequence searches. Search of more than one sequence would constitute a burden on the Office.

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 31 is generic.

Additionally, if Invention III is elected, Applicants must also select **(b)** one of the following species of epitope tags: SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3, SEQ ID NO:4, or SEQ ID NO:5. Although classifications for the epitope tags are overlapping, each represents a patentably distinct species, having different sequences and structures, and requiring separate sequence searches. Search of more than one sequence would constitute a burden on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 31 is generic.

Furthermore, if Invention III is elected, Applicants must also select **(c)** one of the following species of signal sequences: SEQ ID NO:24, SEQ ID NO:25, SEQ ID NO:26, SEQ ID NO:27, or SEQ ID NO:28. Although classifications for the signal sequences are overlapping, each represents a patentably distinct species, having different sequences and structures, and requiring separate sequence searches. Search of more than one sequence would constitute a burden on the Office.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 31 is generic.

Applicant is advised that a reply to this requirement must include an identification of the single species that is elected consonant with each of the three species election requirements, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.



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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicants are advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). To be fully responsive, Applicants must comply with the following:

If Invention I is elected, Applicants must select one species from each of the three (3) types listed, a hydrophobic target protein, an amphiphile, and an epitope tag.

If Invention II is elected, Applicants must select one species from each of the two (2) types listed, a hydrophobic target protein and an epitope tag.

Lastly, if Invention III is elected, Applicants must select one species from each of the three (3) types listed, a hydrophobic target protein, an epitope tag, and a signal sequence.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of

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inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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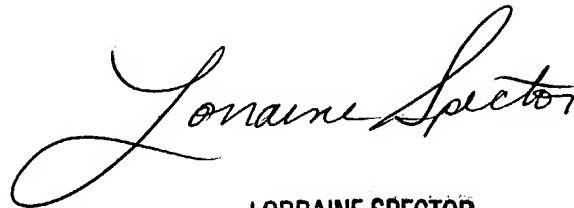
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jon M. Lockard, Ph.D.** whose telephone number is **(571) 272-2717**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Brenda Brumback, Ph.D.** can be reached on **(571) 272-0961**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

JML  
September 27, 2004

A handwritten signature in cursive script that reads "Lorraine Spector". The signature is written in black ink and is positioned above the printed name and title.

**LORRAINE SPECTOR  
PRIMARY EXAMINER**